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(71) Applicants (*for all designated States except US*): MEDISPEC CC [ZA/ZA]; 75 Victoria Street, Somerset West 7130 (ZA). OCTROOIBUREAU KISCH N.V. [NL/NL]; De Ruyterkade 62, Curacao (AN).

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(54) Title: SKIN COMPATIBLE ADHESIVE

(57) Abstract

A skin compatible adhesive is provided for use on skin related medical appliances such as ostomy drainage pouches, wound care drainage bags, etc., which includes a cohesive strengthening component and a least one of the following constituents: a dry–tack component, such as a polyisobutylene; a moisture–absorbent wet–tack component such as a hydrocolloid powder, and a preservative such as pectin and/or antimicrobial agent, the adhesive being characterised in that the cohesive strengthening component comprises a polysiloxane.

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SKIN COMPATIBLE ADHESIVE

INTRODUCTION AND BACKGROUND OF THE INVENTION

THIS invention relates to a skin compatible adhesive, particularly one suitable for use on the skin of human beings.

Skin compatible adhesives are used for securing medical appliances such as wound care drainage bags, ostomy drainage pouches, and accessories, to the skin of patients so that a wound or stoma, can drain directly into such appliances. Skin compatible adhesives should ideally be hypoallergenic and nontoxic and because they are commonly used over an extended period of time, they should remain soft and flexible and should not seep or flow away from the originally adhesive coated areas. In addition the adhesive should not leave a substantial residue on the patient's skin upon removal of the appliance.

PRIOR ART

Known modern skin compatible adhesives commonly use gum or petrochemically related compounds to act as a flexible carrier and to provide dry-tack. Hydrocolloid powders are usually added to provide wet-tack and to absorb moisture and perspiration present on the skin of the patient being treated. A preservative is often added to counter biological attack. A variety of fillers, medicinal powders, colour

pigments etc may also be added, as well as various other substances which may be added for economical or other reasons.

One such known skin compatible adhesive includes polyisobutylene to provide dry-tack, carboxymethylcellulose, karaya and/or guar gum to provide wet-tack and absorb moisture, and pectin as preservative. Many modifications, which vary from manufacturer to manufacturer in order to suit their individual needs, are made according to this general formula.

The aforesaid known skin compatible adhesives suffer from various disadvantages. For example, they are found to seep or flow away from the area on the skin of the patient being treated, thus causing inconvenience to the patient, lack of sufficient adhesion, and/or exterior contamination of the appliances used. A further disadvantage is that the known adhesives are found to harden during extended use, causing patient discomfort. Another disadvantage is that excessive adhesive residue may remain on the skin after an appliance has been removed, thus requiring extra effort to remove, which in turn may result in unnecessary and undesirable skin damage.

OBJECT OF THE INVENTION

It is an object of the invention to provide a skin compatible adhesive which overcomes or at least minimises the aforesaid disadvantages.

SUMMARY OF THE INVENTION

According to the invention a skin compatible adhesive includes a mixture of a cohesive strengthening component and at least one of the following constituents: a dry-tack component; a moisture-absorbent, wet-tack component; and a preservative and/or microbial agent, the adhesive being characterised in that the cohesive strengthening component comprises a polysiloxane.

Applicant has found that the presence of the polysiloxane in the adhesive not only improves its cohesive strength, but also that it renders it more flexible and less likely to harden with time.

Further according to the invention the polysiloxane is a two-part curable one, together with its appropriate catalyst.

Still further according to the invention the polysiloxane is present in the adhesive in a concentration in the order of 1 to 40% (mass/mass) of the total mixture.

Still further according to the invention the dry-tack component is a pressure sensitive one.

Preferably the dry-tack component comprises polyisobutylene.

Preferably also, the polyisobutylene is present in a concentration in the order of 10 to 70% (mass/mass) of the total mixture.

Still further according to the invention the moisture-absorbent wet-tack component comprises a hydrocolloid powder.

Preferably the hydrocolloid powder comprises a mixture of carboxymethylcellulose and karaya gum.

Preferably the hydrocolloid powder is present in a concentration in the order of 5 - 70 % (mass/mass) of the total mixture.

Still further according to the invention the preservative comprises pectin.

Preferably the pectin is present in a concentration in the order of 0,1 to 30% (mass/mass) of the total mixture.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Two embodiments of the invention will now be described with reference to the following examples:

Example 1

309.85g of a skin compatible adhesive according to a first embodiment of the invention was prepared by a method including the steps of:

- mixing 19.74g karaya gum; 84.6g guar gum; 10.15g hydroxypropylmethylcellulose (METHOCEL™); 23.69g sodium carboxymethylcellulose(KICCOLATE Na-CMC™); and 2.82g pectin to obtain a mixture A;
- mixing 0.85g of an OL catalyst (Wacker-Chemie GmbH - 0006677) with 16.5g of component "A" (Wacker-Chemie GmbH - 3004/50 "A") of a two part curable polysiloxane to obtain a mixture B;
- mixing the mixture B with 16.5g of the component "B" (Wacker-Chemie GmbH - 3004/50 "B") of the two part polysiloxane to obtain a mixture C;
- mixing the mixture C with 135g polyisobutylene (VISTANEX LM-MS™) to obtain a mixture D;
- mixing the mixture D for 7 minutes with the mixture A in a suitable mixing apparatus to obtain a mixture E; and
- elevating the temperature of the mixture E to 39°C for a period of 6 hours to cure the two part polysiloxane.

An adhesive having a relatively harder constitution is obtained with this method.

Example 2

322.18g of a skin compatible adhesive according to a second embodiment of the invention was prepared by a method including the steps of:

- mixing 32.16g karaya gum; 32.33g carboxymethylcellulose; and 2.82g pectin to obtain a mixture F;
- mixing 1.87g of the OL catalyst with 38.5g of component "A" of the two part curable polysiloxane to obtain a mixture G;
- mixing the mixture G with 38.5g of the component "B" of the two part polysiloxane to obtain a mixture H;
- mixing the mixture H with 176g polyisobutylene to obtain a mixture I;
- mixing the mixture I for 7 minutes with the mixture F in a suitable mixing apparatus to obtain a mixture J; and
- elevating the temperature of the mixture J to 39°C for a period of 6 hours to cure the two part polysiloxane.

An adhesive having a relatively softer constitution is obtained with this method.

Applicant has found that the skin compatible adhesive according to the invention is ideally suited for use on skin related medical appliances such as ostomy pouches, wound care products, sticking-plaster and

transdermal medication plaster.

Numerous trials revealed that the adhesive according to the invention was not only hypo-allergenic, but also that when compared to the hitherto known products it (i) remains soft and flexible on the patient's skin for a longer period of time; (ii) comes off more cleanly upon removal, even after extensive usage; and (iii) does not seep or flow away from the area on the skin of the patient being treated.

It will be appreciated that the invention also includes within its scope a medical appliance such as an ostomy pouch, a wound care product, sticking-plaster and/or transdermal medication plaster, provided with an adhesive according to the invention.

It will be appreciated still further that there are no doubt many variations in detail possible with a skin compatible adhesive according to the invention, and medical appliances on which it is used, without departing from the spirit and/or scope of the claims.

CLAIMS

1. A skin compatible adhesive which includes a mixture of a cohesive strengthening component and at least one of the following constituents: a dry-tack component; a moisture-absorbent, wet-tack component; and a preservative and/or anti-microbial agent, the adhesive being characterised in that the cohesive strengthening component comprises a polysiloxane.

2. The adhesive of claim 1 in which the polysiloxane is a two-part curable one, together with its appropriate catalyst.

3. The adhesive of claims 1 or 2 wherein the polysiloxane is present in the adhesive in a concentration in the order of 1 to 40% (mass/mass) of the total mixture.

4. The adhesive of any one of the preceding claims wherein the dry-tack component is a pressure sensitive one.

5. The adhesive of any one of the preceding claims wherein the dry-tack component comprises polyisobutylene.

6. The adhesive of claim 5 wherein the polyisobutylene is present in a concentration in the order of 10 to 70% (mass/mass) of the

total mixture.

7. The adhesive of any one of the preceding claims wherein the moisture-absorbent wet-tack component comprises a hydrocolloid powder.

8. The adhesive of claim 7 wherein the hydrocolloid powder comprises a mixture of carboxymethylcellulose and karaya gum.

9. The adhesive of claims 7 or 8 wherein the hydrocolloid powder is present in a concentration in the order of 5 - 70% (mass/mass) of the total mixture.

10. The adhesive of any one of the preceding claims wherein the preservative comprises pectin.

11. The adhesive of claim 10, wherein the pectin is present in a concentration in the order of 0,1 to 30% (mass/mass) of the total mixture.

12. A skin compatible adhesive substantially as herein described with reference to the examples.

13. A method of manufacturing a skin compatible adhesive substantially as herein described with reference to the examples.

14. A skin related medical appliance such as an ostomy pouch, a wound care product, sticking-plaster and/or transdermal medication plaster and the like which is provided with an adhesive as defined in any one of claims 1 to 12.

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X A	EP 0 315 333 A (DOW CORNING) 10 May 1989 see page 2, line 1 - line 48 see page 3, line 27 - line 30 see page 4, line 20 - line 45 see page 5, line 24 - line 35; claims 1,13-17; examples 3-5	1-10 11-14
X A	WO 91 09633 A (MINNESOTA MINING & MFG) 11 July 1991 see page 3, line 26 - page 4, line 14 see page 6, line 17 - line 20 see page 9, line 14 - line 20 see page 11, line 5 - page 12, line 3 see page 13, line 5 - line 13 see page 14, line 30 - line 37 see page 23, line 12 - line 29 see page 26, line 33 - page 27, line 1 see page 27, line 18 - line 26	1,2 3-14

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[X] Further documents are listed in the continuation of box C.

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